

analysis was performed with the Mainland-Gart test and the Fisher exact test. Subjects were also asked to fill out a generic QoL questionnaire (the Functional Assessment of Cancer Therapy-General [FACT-G]) at the beginning of each cycle and on day 14 with the Subject Outcome Questionnaire (SOQ), which evaluates levels of pain, discomfort, inconvenience, satisfaction, etc. **RESULTS:** Of the 76 randomised patients, 74 took study medication, 4 discontinued, making a total of 70 evaluable subjects. Overall, 58 patients preferred pegfilgrastim (83%; $p < 0.001$) after 2 cycles. Significantly more patients preferred pegfilgrastim when starting with filgrastim first (94% versus 73%, $p < 0.001$), indicating a clear sequential effect. The main reason for the overall preference of pegfilgrastim was dosing simplification, safety and less pain. Overall, mean SOQ scores were better in the pegfilgrastim arm (87.5% versus 78.9% in the filgrastim arm, $p < 0.05$). Differences in specific SOQ areas were predominantly found in the pegfilgrastim arm. FACT-G scores showed no significant differences between treatment arms and cycles. **CONCLUSION:** Subjects demonstrated a very strong preference for pegfilgrastim (83%), primarily because of dosing simplification. A higher proportion also reported less pain, discomfort and inconvenience, as well as greater treatment satisfaction.

PEN2 I**COMPARISON OF PAIN OUTCOMES AND HRQL USING THE TREATMENT OUTCOMES IN PAIN SURVEY (TOPS) IN CANCER-RELATED PAIN**

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OBJECTIVES: Treatment Outcomes in Pain Survey (TOPS) characterizes pain and health-related quality of life (HRQL) with chronic nonmalignant pain (CNMP). TOPS has 8 subscales from SF-36 Health Survey and 14 TOPS domains measuring physical, functional, and psychosocial status. We evaluated TOPS in cancer-related pain. **METHODS:** TOPS was administered to 150 patients with advanced cancer-related pain at three US academic hospitals. Data were collected on demographic variables, primary site of cancer, and cancer treatment status. Pain was measured on a visual analogue scale. Internal consistency reliability (Cronbach's alpha) was assessed for the 8 TOPS SF-36 subscales and 14 TOPS domains. Cases were compared by treatment status, physiologic sources of pain, and pain severity using Student-t tests and the Mann-Whitney U tests. **RESULTS:** Physical, functional, and psychosocial status differed by treatment status. There were no significant differences in TOPS SF-36 and TOPS domains for subjects experiencing neuropathic compared to non-neuropathic pain. However, those with somatic pain reported greater Body Pain ($p = 0.001$) and Pain Symptoms ($p < 0.05$), and had worse

Total Pain Experience ($p < 0.05$). Greater pain was associated with significantly poorer outcomes on 5 of the 8 SF-36 subscales, with more Pain Symptoms ($p < 0.001$), greater family disruptions ($p < 0.001$), poorer Passive Coping ($p < 0.05$), and less Patient Satisfaction with Outcomes ($p < 0.01$). Reliability for SF-36 subscales and TOPS domains were all > 0.70 , similar to prior TOPS usage in CNMP. **CONCLUSIONS:** TOPS demonstrated acceptable reliability with cancer-related pain and detected significant differences by treatment status, source of pain, and pain severity. That TOPS SF-36 and TOPS domains differed by pain severity supports its validity as a measure to assess pain outcomes and HRQL in cancer. TOPS may also be a useful clinical tool to identify patients at risk for impaired physical function, symptoms, emotional distress, disruptions in social relationships, and negative perceptions of satisfaction with health care.

HEMATOLOGICAL DISORDERS/LEG ULCERS/ PITUITARY GLAND DISORDERS**HEMATOLOGICAL DISORDERS & LEG ULCERS— Clinical Outcomes Studies****PHL I****HEMOGLOBIN LEVELS ASSOCIATED WITH DIAGNOSIS OF ANEMIA**

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OBJECTIVE: To examine the association between hemoglobin levels and anemia diagnosis and to determine the hemoglobin level that is most likely to trigger diagnosis in oncology patients. **METHODS:** Members of a large US health plan with an oncology diagnosis and chemotherapy claims between January 1, 2002 and February 28, 2002 were included in this retrospective claims database analysis. Medical and laboratory claims were examined to identify chemotherapeutic episodes, International Classification of Diseases 9th Modification (ICD-9) codes for anemia, and hemoglobin values within each episode and immediately preceding new anemia diagnoses. Descriptive statistics and multivariate regression were used to examine the relationship between anemia diagnosis and hemoglobin values. **RESULTS:** A total of 3180 chemotherapeutic episodes corresponding to 2717 oncology patients were identified. In episodes in which the hemoglobin dropped below 12g/dL (1689 episodes; 53%), an anemia diagnosis occurred in only 733 episodes (45%). Additionally, an anemia diagnosis was found in only 66% of the episodes where hemoglobin fell below 10.0g/dL. Being over 50 years old, having Non-Hodgkins Lymphoma, and having fatigue or renal disease were observed to increase the odds of diagnosis controlling for hemoglobin nadir values and chemotherapeutic agent.

Adjusting for age above 50 years old, gender and breast cancer, the mean hemoglobin value prior to anemia diagnosis was 11.2 g/dL (95% CI; 11.0, 11.3). **CONCLUSION:** These data suggest that many patients who become anemic during chemotherapy (\geq Grade 1 anemia) do not receive an anemia diagnosis. At hemoglobin values below 10 g/dL, the level at which the National Comprehensive Cancer Network (NCCN) most strongly recommends consideration of aggressive anemia treatment, only two-thirds of patients were identified as anemic by an ICD-9 code. Our findings provide evidence that identifying patients with ICD-9 codes for anemia from claims data may be misleading and can significantly underestimate the true number of patients with anemia.

PHL2**PROBABILITY OF INITIATING ERYTHROPOIETIC THERAPY**

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OBJECTIVE: Chemotherapy-induced anemia is a concern in oncology patients. The objective of this study was to assess patterns of treatment with erythropoietic therapy among oncology patients in a managed care setting, and compare with the National Comprehensive Cancer Network (NCCN) cancer and treatment-related anemia clinical practice guideline recommendations. **METHODS:** Members of a health plan who received chemotherapy and erythropoietin and had access to laboratory result data between January 1, 2002 and February 28, 2002 were included. Data were analyzed to examine factors that were significantly associated with use of erythropoietic therapy stratified by nadir hemoglobin categories. **RESULTS:** A total of 2560 patients were identified. Erythropoietic therapy was initiated in 615 (45%) patients whose hemoglobin dropped below 12 g/dL, 443 (52%) patients whose hemoglobin dropped below 11 g/dL (NCCN hemoglobin level to consider erythropoietic therapy), and 275 (62.5%) patients whose hemoglobin dropped below 10 g/dL (NCCN hemoglobin level to strongly consider erythropoietic therapy). Multivariate analysis revealed that the mean probability of receiving erythropoietic therapy was 0.34 (95% CI; 0.27–0.42) for patients whose hemoglobin fell between 10.5 g/dL and 10.9 g/dL; 0.44 (0.36–0.53) for patients who reached a low between 10.0 g/dL and 10.4 g/dL; and 0.67 (0.61–0.72) for patients who dropped below 10.0 g/dL controlling for cancer type, blood administration, filgrastim and select chemotherapeutic usage, hypertension and diagnosis of anemia. Patients who received erythropoietic therapy were initiated following a mean adjusted hemoglobin of 10.4 g/dL (10.3 g/dL–10.6 g/dL). **CONCLUSIONS:** These data suggest a treatment gap in patients whose hemoglobin levels drop below thresholds set by the NCCN guidelines.

HEMATOLOGICAL DISORDERS & LEG ULCERS—Cost Studies**PHL3****COST-EFFECTIVENESS OF HAEMOPHILIA TREATMENT: A CROSS-NATIONAL ASSESSMENT**

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Haemophilia treatment is very expensive and therapy has to be life-long. In comparison with other diseases—e.g., diabetes—haemophilia is rare occurring in approximately 1:10,000. **OBJECTIVE:** To determine the incremental cost-effectiveness of prophylactic treatment compared with on-demand treatment in patients with haemophilia over a 1-year period from the third-party payers' perspective. **METHODS:** A decision-tree model was developed to compare clinical outcomes, quality-adjusted life years, and costs of prophylactic vs. on-demand treatment for three European countries: Germany, Sweden, and the United Kingdom. The time horizon of the decision-analytic model was one year. Health effects were presented in terms of quality-adjusted life years gained (QALYs) and in avoided bleeds as clinical outcome. **RESULTS:** A total of 506 patients were included. Incremental cost-effectiveness ratio (ICER) for prophylactic treatment in one year for HIV-infected patients younger than 30 years ranged from €1.24 million/QALY (Germany) to €1.73 million/QALY (United Kingdom). For Sweden, the ICER could not be calculated, because all patients younger than 30 received prophylactic treatment. For HIV-negative patients younger than 30 years, ICER ranged from €2.21 million/QALY (Germany) to €3.10 million/QALY (UK). These values were higher than in the HIV-infected group, because the incremental effectiveness of prophylactic treatment was smaller in HIV-negative patients. In patients older than 30 years, ICERs were even higher in HIV-negative patients, ranging from €4.77 million/QALY (Germany) to €5.7 million/QALY (Sweden and UK). In HIV-infected persons older than 30, on-demand treatment dominates prophylactic treatment. Prophylactic treatment was more expensive but yielded slightly lower QALY values. **CONCLUSION:** Based on our analysis and within the limitations of our short-term model, prophylactic treatment has an extremely high cost-effectiveness ratio when only a 1-year time horizon is considered. Further research should focus on the long-term consequences of the examined strategies.